



Dr. Richard Lysakowski,  
Executive Director

February 27, 2002

U. S. Environmental Protection Agency  
Enforcement and Compliance Docket  
and Information Center (2201A)  
Attn: Docket No. EC-2000-007  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

**SUBJECT:** Request for Withdrawal of EPA's proposed Cross-Media Electronic Reporting and Recordkeeping Rule (CROMERRR) as written and published in the Federal Register on August 31, 2001

The Collaborative Electronic Notebook Systems Association (CENSA) is a global market development association of leading pharmaceutical, chemical, and biotechnology companies and innovative automation system suppliers. As a major industry group focused on electronic recordkeeping and electronic laboratory notebooks, our members and many other organizations in the private and public sectors would be significantly and negatively impacted by the proposed Cross-Media Electronic Reporting and Recordkeeping Rule (CROMERRR) as currently written.

The following CENSA comments on CROMERRR focus on five main areas of concern:

1. CROMERRR definition of an "electronic record" and recordkeeping requirements
2. The "voluntary" nature of CROMERRR
3. The financial burden and adverse economic impact
4. The fraud prevention aspects of CROMERRR
5. CROMERRR and the Government Paperwork Elimination Act (GPEA)

## **1. CROMERRR Definition of an "Electronic Record" and Recordkeeping Requirements**

CROMERRR defines an electronic record as "any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system." In effect, this would identify an electronic record as any data or documents created in the normal course of business. This definition is too broad and from an evidentiary perspective emphasizes that all data tangentially

affected by computers are electronic records. While it is true that all data and records may be used in court as evidence, it is not conversely true that all evidence is a record. The CROMERRR definition is incongruent with and overreaches common business recordkeeping principles. It does not present or describe the key attributes of an electronic record. CENSA recommends that the EPA work with the archival and records management communities to select or develop a formal definition and criteria for electronic records that will meet the EPA's and industry's performance-based objectives for electronic records.

CENSA recommends that this performance-based definition and criteria combine key attributes of quality electronic records such as the use of long-term preservation formats to ensure authenticity and access, and the custodianship role of the records manager or archivist to ensure continued access and authenticity of the electronic record for as long as needed by the business. Also, separation of duties is an important and fundamental principle of quality practices for accounting and recordkeeping. The separation of recordkeeping responsibilities from the responsibilities of the electronic records creator is important to ensure the long-term preservation and access of electronic records. CROMERRR appears to assume that all scientists, engineers, and office workers that use data systems are willing and able to perform the recordkeeping functions normally carried out by trained records managers and archivists.

CROMERRR also implies that every computer system and software application used in business is a recordkeeping system. The design center of software on the market today – and since the dawn of computers – has focused on productivity increases for users; it has not included “recordkeeping for as long as needed by the business.” For many records this means long-term preservation and access (many years to decades, possibly even centuries). This new design center (long-term preservation and access to electronic records) is just now starting to be recognized as important in newer software systems. However, this has just been recognized and it will take years for government and industrial systems to understand and implement the requirements correctly. Electronic records require special care and maintenance to ensure ongoing access and authenticity. CROMERRR's concept that every computer system and software application used in business is already a recordkeeping system has far-reaching implications and it is unclear how industry or government could meet the CROMERRR requirements within the time frame outlined in the proposed regulation. One prominent example is common spreadsheet applications that do not have functionality to meet the audit trail requirements stated in CROMERRR.

## **2. “Voluntary” Nature of CROMERRR**

CENSA member organizations have been generating and maintaining a variety of electronic data and evidence in support of EPA-regulated programs for many years. When the EPA states, “electronic document submission or electronic record-keeping will be totally voluntary” it is unclear what the intention is for the regulated community already creating maintaining data and evidence in electronic format.

Creating and maintaining data and evidence electronically is no longer a voluntary decision. Government and industrial business activities demand the use of computers to support business requirements, processes, and innovation. Regulated entities must use computers to generate, process, and retain data. Since the entire regulated community will be held to CROMERRR requirements for electronic data and evidence and since that community will continue to generate electronic data and evidence, compliance is no longer voluntary. Halting the use of systems to do ongoing electronic data management, the only apparent "voluntary" alternative to meeting the proposed requirements, would be commensurate with halting the use of computers and reverting to paper-based business processes. The regulated community in industry and government would suffer too much business loss from discontinuing existing its current use of electronic data and information systems for electronic evidentiary recordkeeping practices.

### **3. Financial Burden and Adverse Economic Impact**

The EPA analysis of financial burden to the regulated community is underestimated. Compliance with CROMERRR would cost industry at least hundreds of millions of dollars. In addition, the number of entities that will be subject to CROMERRR recordkeeping requirements is much larger than the EPA estimate of 428 facilities since CROMERRR would impact research, development, manufacturing, and other types of industrial and government facilities, plus many types of commercial retail businesses that have an impact on the environment.

Also, the assumption by EPA that the capital cost to implement CROMERRR is a one-time fee is unrealistic since technology changes rapidly and the recurring capital costs of upgrades must be factored in. Upgrades to computer systems generally prove costly since they usually require new supporting operating systems, database management systems, and other related capital expenditures. The regulated community will incur costs for upgrading existing systems to meet CROMERRR electronic recordkeeping requirements, audit trail requirements, implementation, training, and validation. Validation alone for large systems usually costs hundreds of thousands of dollars.

Proposed requirements for archiving electronic records for the retention times required by EPA would pose an additional financial burden on the regulated community. The costs and resources associated with long-term archival storage and retrieval of electronic data have yet to be clearly defined. Even a centralized authority like the United States National Archives and Records Administration (NARA) admit they do not clearly understand the full impact electronic records will have on their business and are in the early stages of research and development of in-house systems to try to meet their needs. It will take years before small, medium, and large scale commercially available and supported electronic records archiving systems are available that meet the needs of business as specified in CROMERRR, e.g., "retention of records in accessible form for as long as needed by the business." Additional cost issues include the cost of continual migration of records collections, or alternatively, the cost of maintaining obsolete hardware or software *and the personnel* to ensure continued functional capability and access to records in authentic form.

CROMERRR states, "EPA will only begin to allow electronic records to satisfy a specific EPA recordkeeping requirement once EPA has provided public notice stating that electronic records will satisfy the identified requirement." CENSA members have been fulfilling EPA program requirements in electronic format for many years. This has included generating, manipulating, analyzing electronic data and reporting electronically. Significant business disruption will occur if EPA requires the regulated community to discontinue its long-standing practices of maintaining data and evidence electronically until such programs can be approved under CROMERRR.

CENSA recommends a new, more comprehensive cost-benefit analysis be performed to address the concerns stated above. This cost-benefit analysis should include the impacts of CROMERRR implementation on industrial and government businesses of all sizes since it would place an especially serious burden on small businesses and on all businesses that run on tight profit margins.

#### **4. The Fraud Prevention Aspects of CROMERRR**

The use of CROMERRR to deter and punish fraud in electronic recordkeeping does not appear to be justified based on either prior history or current need. Also, as EPA already has strong anti-fraud provisions defined in its Good Laboratory Practices (GLPs) and Good Automated Laboratory Practices (GALPs), the CROMERRR requirements appear redundant. Accordingly, CENSA recommends that EPA conduct a separate risk and anti-fraud cost-benefit analysis.

#### **5. CROMERRR and the Government Paperwork Elimination Act (GPEA)**

GPEA was intended to assist in the voluntary reduction of paperwork and to benefit regulated facilities by precluding less favorable treatment of electronic records. The intent of GPEA was not to impose burdensome regulations on industry. CROMERRR, as a stated means by which the EPA hopes to meet GPEA requirements, in effect forces industry to meet newly proscribed EPA electronic records retention requirements. This overreaches the intent of GPEA and the imposition of new regulations would have a net negative impact on the organizations that GPEA is intended to serve.

## **CENSA RECOMMENDATIONS TO THE EPA**

Based on the above concerns, CENSA respectfully requests that the EPA withdraw and then reevaluate CROMERRR. CENSA also recommends that in its reevaluation of CROMERRR the EPA split the proposed requirements into the following separate rules and implement them in phases:

### **1. Environmental Reporting**

This section of CROMERRR appears to be a useful and workable proposal. CENSA, however, recommends that the EPA review the problems of other government agency electronic submission processes prior to re-submission of this proposal. Many other agencies have electronic reporting and application processing systems in place that could provide additional guidance to the EPA in the review process.

### **2. Records Retention**

CENSA recommends that this section be withdrawn. Key recordkeeping terms and requirements need to be redefined. They must be performance-based and include criteria for preservation formats, quality processes for migration, authenticity verification, validation, auditing, etc., so that government and industrial businesses clearly know what is expected of them. The world of electronic records is a full paradigm shift from paper records and requires complete rethinking to meet our common goals. Recordkeeping and archiving issues such as long-term preservation formats, conversion and migration of legacy systems, long-term access, and records custodianship must be addressed. Also, more detailed cost impact analyses must be performed.

### **3. Evidentiary Data Collection for Fraud Detection and Criminal Prosecution**

This section could be proposed as a separate rule after a risk and anti-fraud cost-benefit analysis is performed.

CENSA thanks you for the opportunity to comment on CROMERRR. We encourage you to work with CENSA and take advantage of the results of our many years of collaborative research and development in many areas directly covered by CROMERRR. If you have any questions concerning our comments, please contact me at 781-935-9600.

Sincerely,

**Dr. Richard Lysakowski**  
**Executive Director**



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02/27/02 04:28 PM

To: docket.oeca@epamail.epa.gov  
cc: mklayman@erecordscentral.org  
Subject: Public Docket Number EC-2000-007 Response to CROMERRR  
from CENSA on February 27th, 2002

Dear Sirs,

Here is CENSA's response to the Public Docket Number EC-2000-007 Response for submissions of comments and recommendations on the EPA's Cross Media Electronic Recordkeeping and Reporting Regulation.

I have included CENSA's in 3 different formats so that you have the greatest chance of being able to receive it and read it.

wpd.doc is WordPerfect 5.X for Windows.

.doc from MS-Word Office 2000 Edition

PDF from Adobe Acrobat V5, saved in version 4 and version 3 accessible, secure format.

We hope that this feedback and recommendations are well received. We think the EPA has done a remarkable job in approaching this enormously difficult task for the United States and all the private and public sector constituencies that it serves. Industry and government businesses will be impacted enormously by CROMERRR in whatever final form results.

Thank you for the opportunity to provide feedback and recommendations.

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